



UNITED STATES PATENT AND TRADEMARK OFFICE

CH
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/004,118	10/30/2001	Stanford Mark Moran	BMED-004/01US	8022
37509	7590	06/09/2006	EXAMINER	
DECHERT LLP P.O. BOX 10004 PALO ALTO, CA 94303			SEHARASEYON, JEGATHEESAN	
			ART UNIT	PAPER NUMBER

1647

DATE MAILED: 06/09/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/004,118	Applicant(s) MORAN, STANFORD MARK	
	Examiner Jegatheesan Seharaseyon, Ph.D	Art Unit 1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-17, 19, 20, 22, 24-27, 29-33, 35-38, 40-47, 49-54 and 68-88 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-17, 19, 20, 22, 24-27, 29-33, 35-38, 40-47, 49-54 and 68-88 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This Office Action is in response to Applicants remarks filed 3/28/2006, which has been entered. Claims 2-17, 19, 20, 22, 24-27, 29-33, 35-38, 40-47, 49-54 and 68-83 have been amended. Claim 28 has been cancelled. Claims 2-17, 19, 20, 22, 24-27, 29-33, 35-38, 40-47, 49-54 and 68-88 are pending and under consideration in the instant Office Action.

2. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 103, maintained.

3. The rejection of claims 2, 3, 8, 10, 14-17, 19, 22, 24, 28, 30, 33-38, 40-47, 49-54, 68-77 and 84-85 (new) under 35 U.S.C. 103(a) as unpatentable over Sorenson in view of Palmeri and Harper is maintained for reasons of record in the Office Actions dated 18 March 2004, 15 December 2004 and 28 September 2005.

The instant invention is drawn to a method of treating an interferon-responsive disorder in a subject comprising determining a well-tolerated, therapeutic pharmacokinetic profile for interferon therapy in a subject by administration of one or more interferons formulated for short-term delivery to the subject and monitoring the subject for therapeutic and adverse effects; and administering to the subject using at least one internally presented, not externally programmable pump one or more interferons formulated for long-term delivery in which the interferons are released from the pump at a rate that substantially achieves the pharmacokinetic profile during long-term delivery.

Applicants' arguments have been fully considered but have not been found to be persuasive. It is also noted that one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As argued previously Applicants continue to argue that the cited art does not support the obviousness rejection. Applicants argue that Sorenson et al. provide a subject with an initial peak level of drug concentration that is followed by lower maintenance levels (see page 16 of the response filed 3/28/06). Thus, the initial drug concentration of Sorenson et al. is reduced and is not substantially achieved over the period of long-term delivery. Contrary to Applicants assertions, as indicated previously (18 March 2004), the Sorenson reference was included to teach a device and methods for introducing a therapeutic agent for a first interval (short term), the introducing the same agent at a second level for the purpose of maintenance (column 2, lines 10-21). Interferons are specifically taught in column 7, line 1.

Applicants assert that Palmeri et al. does not cure the deficiencies of Sorenson et al. Palmeri et al. reference was included to teach the administration of different levels of interferon to achieve an optimal dosage. Contrary to Applicants' assertion that Palmeri et al. do not disclose a well-tolerated, therapeutic pharmacokinetic profile for interferon therapy, the reference does disclose the maximally tolerated interferon dose (page 330). Thus, the reference demonstrates, by studying different interferon doses (short-

Art Unit: 1647

term), a well-tolerated interferon dose (maximum tolerated dose) for long-term administration.

Although Applicants assert that Harper et al. reference does not teach or suggest determining a well-tolerated, therapeutic pharmacokinetic profile for interferon therapy, the Harper et al. reference was provided by the Office to teach an implantable pump used for long-term administration of interferons. Harper et al. also disclose that U. S. Patent No. 5, 728, 396 teaches an implanted osmotic pump where the infusion rate cannot be adjusted (column 2, lines 5-20).

Contrary to Applicants assertion that references alone or in combination at least do not teach or suggest determining a well-tolerated, therapeutic pharmacokinetic profile for interferon therapy, as was stated in the previous Office Actions, Palmeri teaches a problem (long-term administration of optimized doses of interferon for the treatment of colorectal carcinoma) that can be solved by the method of Sorenson and Harper teaches pumps that are useful for that method. Thus it would have been obvious to the artisan of ordinary skill to combine them, resulting not in merely the combination of two pumps and a study but in a method of altering drug levels to optimize doses by administering a first formulation followed by a second formulation using an internal pump. Alternatively, administering the short-term formulations outside the pump mechanism to determine the suitable dosages for long-term administration and later administering the long-term formulations using an internal pump into the subject.

Art Unit: 1647

Applicants also assert that the Office makes an unsupported conclusion regarding the problem of Palmeri et al. and its resolution by the application of Sorenson et al. and Harper et al. However, Sorenson teaches a method of optimizing interferon doses in which a first level and then a second level is given. Palmeri teaches a need for such optimization and Harper teaches a implantable pump that is useful for such optimized administration. The combination of Sorenson, Palmeri, and Harper suggests to the artisan of ordinary skill a method of treatment that optimizes interferon doses by administering a first level and then administering a second level, using an internal pump. Furthermore, the courts have held that:

Specific statements in the references themselves which would spell out the claimed invention are not necessary to show obviousness, since questions of obviousness involves not only what references expressly teach, but what they would collectively suggest to one of ordinary skill in the art. See CTS Corp. v. Electro Materials Corp. of America 202 USPQ 22 (DC SNY 1979); and In re Burckel 201 USPQ 67 (CCPA 1979).

and

In considering the disclosure of a reference, it is proper to take into account not only specific teaching of the reference but also the inferences which one skilled in the art would be reasonably be expected to draw therefrom In re Preda, 401 F.2d 825, 159 USPQ 342, 344 (CCPA 1968).

and

it is not necessary that the claimed invention be expressly suggested in any one or all of the references to justify combining their teachings; rather the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981).

Therefore rejections of record are maintained for reasons of record.

Art Unit: 1647

4. The rejection of claims 3-7, 12, 13, 19, 20, 22, 24, 25-27, 29, 32, 33, 68, 74, 78-83 and 86-88 (new) under 35 U.S.C. 103(a) as unpatentable over Sorenson in view of Palmeri and Harper and further in view of Johnson is maintained for reasons of record in the Office Actions dated 18 March 2004, 15 December 2004 and 28 September 2005.

The Office agrees with the Applicants that the independent claims were not included in the previous rejections. However, the claims are now included in the rejection of the instant rejection. Applicants' arguments with respect to Sorenson, Palmeri and Harper have been addressed above in paragraph 3. Applicants assert that Johnson et al. reference does not cure the deficiency of the Sorenson, Palmeri and Harper references. This is not found to be persuasive because Johnson reference was included to teach the various types of interferons and their use in the treatment of disease. Therefore as stated previously in the Office Actions dated 18 March 2004, 15 December 2004, 28 September 2005 and above the rejections of record are maintained.

5. The rejection of claims 2, 11, 22, 31, 68 and 74 under 35 U.S.C. 103(a) as unpatentable over Sorenson in view of Palmeri, Harper, and Johnson and further in view of Kwan is maintained for reasons of record in the office action of 18 March 2004, 15 December 2004 and 28 September 2005.

The Office agrees with the Applicants that the independent claims were not included in the previous rejections. However, the claims are now included in the

Art Unit: 1647

rejection of the instant rejection. Applicants' arguments with respect to Sorenson, Palmeri, Harper and Johnson have been addressed above in paragraph 4. Applicants assert that Kwan et al. reference does not cure the deficiency of the Sorenson, Palmeri, Harper and Johnson references. This is not found to be persuasive because Kwan reference was included to teach a pharmaceutical composition of interferons that retards microbial growth for longer than four weeks and teaches the advantages of such compositions. Therefore as stated previously in the Office Actions dated 18 March 2004, 15 December 2004, 28 September 2005 and above the rejections of record are maintained.

6. New grounds of rejections necessitated by Applicant amendments.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7a. Claims 68 and 74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a new matter rejection.*

The term "internally presented, not externally programmable pump" has no support in the specification. The Applicants are required to cancel the new matter in the reply to this Office Action.

8.The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 68 recites the limitation "said pharmacokinetic profile during said long-term delivery" on line 9. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

9.Claims 2-17, 19, 20, 22, 24-27, 29-33, 35-38, 40-47, 49-54 and 68-88 rejected under 35 U.S.C. 103(a) as being unpatentable over Sorenson in view of Palmeri, Peery et al. (U. S. Patent No. 5, 728, 396), and Johnson and further in view of Kwan.

The teachings of Sorenson, Palmeri, Johnson and Kwan are discussed extensively above in paragraphs 3, 4, 5 and in Office Actions dated 18 March 2004, 15 December 2004 and 28 September 2005. Peery et al. disclose an osmotic pump that is implanted. It also discloses that this pump once implanted has no mechanism to change the infusion rate (column 15, lines 35-45), therefore, meeting the newly introduced limitations of claims 68 and 74. Peery et al also teach that the delivery is expected to last at least one year at this rate. Therefore, it would have been obvious to one ordinary skill in the art to substitute the pump taught by Peery et al. for that taught by Sorenson et al. because it would function for an extended period (long-term delivery) infusing

Art Unit: 1647

medication. One of ordinary skilled would have been motivated to do so because they have the same function and would be expected to be useful for the same function and would be expected to be useful for the same purposes, with the benefit of long-term delivery. Therefore, claims 2-17, 19, 20, 22, 24-27, 29-33, 35-38, 40-47, 49-54 and 68-88 are rejected under 35 U.S.C. 103(a) as unpatentable over Sorenson in view of Palmeri, Peery et al. (U. S. Patent No. 5, 728, 396), and Johnson and further in view of Kwan.

10. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback can be reached on 571-272-0961. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

**CHRISTINE J. SAUD
PRIMARY EXAMINER**

Christine J. Saud

Art Unit: 1647

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JS 05/06